DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M2933h

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

**VIA FEDERAL EXPRESS**

September 9, 1999

Frank Camacho, General Manager
Port Authority of Guam
1026 Cabras Way #201
Piti, Guam 96925

## WARNING LETTER

Dear Mr. Camacho:

On August 4, 1999, FDA Investigator Lorna F. Jones conducted an inspection of your drinking water systems at Piers F3, F4, F5, and F6 located in Piti, Guam. Your operations at these piers are in serious violation of the federal regulations for interstate conveyances, Title 21, Code of Federal Regulations, Part 1250 (21 CFR 1250), and Section 361 of the Public Health Service Act.

The Investigator observed brown, cloudy water in the pit containing the potable water hydrant. This brown, cloudy water was observed entering the uncapped end of the potable water hydrants in three locations. Empty soda cans, paper, plastic, and other refuse were observed in direct contact with all the hydrant pits. The seven potable water outlets lack protective caps, and potable water hoses used to fill drinking water tanks on vessels using the port were stored outside without protective caps. The lack of proper back flow prevention devices on all potable water hydrants was observed on the potable water hydrants. The hydrants were found to be equipped with double check valves (back flow preventors) where reduced pressure zone devices are required. These inspectional findings were listed on form FDA-483 (copy enclosed) and discussed with Frank Santos, Harbor Master, at the conclusion of the inspection.

Your facility is being classified "Provisional" because of these deficiencies. A classification of "Provisional" means that if the violations are not corrected within thirty (30) working days from receipt of this notification, your firm may be placed on "NOT APPROVED", use prohibited status. "NOT APPROVED" means that vessels in your port will be prohibited from using the water supply for drinking water purposes until the violations have been corrected and the facility has been re-inspected by FDA.

You should take prompt action to correct these deficiencies. Failure to do so may result in appropriate regulatory action, such as seizure and/or injunction without further notice.

You should notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violations, including an explanation of preventive measures taken to preclude recurrence of similar violations. If corrective action cannot be competed within fifteen

working days, cite the reason for the delay and the time by which the corrections will be completed. Your response should be sent to:

Randall P. Zielinski, CSO/ITS
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

You may wish to FAX your response to Mr. Zielinski at (510) 337-6703.

Sincerely,

Patricia C. Ziobro

Patricia C. Ziobro
Director
San Francisco District

Enclosures:

FDA 2521, Inspection Summary-Vessel Watering Point Sanitation dated August 4, 1999
FDA 483, Inspectional Observations, dated August 4, 1999

Cc: Annabelle L. Cruz
Chief
Department of Public Health & Social Services
Division of Environmental Health
P.O. Box 2816
Hagatna, Guam 96932

**BIORESEARCH MONITORING WARNING LETTER OR NOTICE OF INITIATION OF DISQUALIFICATION PROCEEDING AND OPPORTUNITY TO EXPLAIN (OR OTHER RECORD POSTED ON THE INTERNET)**

DATE: September 15, 1999

TO: Director, Freedom of Information Staff (HFI-35)

FROM:
Division of Bioresearch Monitoring
Center for Devices and Radiological Health (HFZ-312)

RE: Placement of Record on the Internet

Please categorize and post the attached record (describe it) Warning Letter dated Sept. 10, 1999 as follows:

1. SUBJECT INDEX (Check one):

_____ Clinical Investigator (Should be listed under the individual's name and not the name of the institution or establishment.)

_____ Institutional Review Board

_____ NIDPOE--Initiates Disqualification Procedure (Should be listed under the individuals name and not the name of the institution or establishment.)

_____ Sponsor Obligations

✓ Good Laboratory Practice

2. COMPANY NAME: University of South Florida

3. CENTER NAME: Nonclinical Laboratory

If you have any questions about posting this letter, please contact:

Name: Rodney T. Albritton Phone: 301-594-4723 FAX: 301 594-4731

Center: HFZ-312, CDRH

Thank you